UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

SOUTHWEST PHARMACY SOLUTIONS, INC.; dba AMERICAN PHARMACIES,	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. C-11-227
CENTERS FOR MEDICARE AND MEDICAID SERVICES, *et al*,	§	
Defendants.	§	

ORDER DISMISSING COMPLAINT

Before the Court is the Defendants' Motion to Dismiss (D.E. 19). Defendants challenge this Court's subject matter jurisdiction. For the reasons set out below, the Motion is GRANTED and the Plaintiff's claims are DISMISSED.

I. Introduction

Plaintiff has sued Defendants, as administrators of the Medicare Part D prescription drug programs, alleging that a "preferred pharmacy" rule allows prescription drug plans to exclude independent pharmacies from their preferred networks in violation of the Medicare requirement that the prescription drug programs apply equally to "any willing pharmacy." 42 U.S.C. § 1395w-104(b)(1)(A) ("any willing pharmacy provision); 42 C.F.R. § 423.120(a)(9) (preferred pharmacy provision). *See* Complaint, D.E. 1. The result is that patients enrolled in such prescription drug plans are charged a higher copayment or coinsurance for their prescriptions if they use an independent pharmacy. Plaintiff cites federal question jurisdiction under 28 U.S.C. § 1331 with respect to Title

XVIII of the Social Security Act, the federal Administrative Procedure Act, and the federal Declaratory Judgment Act. D.E. 1.

Defendants have responded with their Motion to Dismiss, claiming that the Plaintiff cannot bring this claim in federal court in the first instance because all claims relating to the Medicare program must first be submitted to the Secretary of the Department of Health and Human Resources for exhaustion of administrative remedies. D.E. 19. Defendants also challenged the Plaintiff's standing to bring the claim asserted, but later withdrew that challenge. D.E. 19, 28, p. 6, n.1.

II. Legal Standard for Motion to Dismiss Based on Lack of Jurisdiction

Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377, 114 S.Ct. 1673 (1994); *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 288-89, 58 S.Ct. 586 (1938). Because "subject-matter jurisdiction is an 'Art. III as well as a statutory requirement[,] no action of the parties can confer subject-matter jurisdiction upon a federal court.' " *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003) (quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702, 102 S.Ct. 2099 (1982)). On a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject-matter jurisdiction. *Kokkonen*, 511 U.S. at 377, 114 S.Ct. 1673.

Because subject-matter jurisdiction focuses on the court's power to hear the claim, however, the court must give the plaintiff's factual allegations closer scrutiny when

resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion for failure to state a claim. *Macharia v. United States*, 334 F.3d 61, 64, 69 (D.C. Cir. 2003); *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). Moreover, the court is not limited to the allegations contained in the complaint. *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64, 107 S.Ct. 2246 (1987). Instead, to determine whether it has jurisdiction over the claim, the court may consider materials outside the pleadings. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. Discussion of Authorities

Because the Plaintiff's complaint, in substance, is governed by Title XVIII of the Social Security Act, the Court first notes that "miscellaneous provisions" of that Title include an incorporation of the administrative exhaustion requirements found in 42 U.S.C. § 405(h). *See generally*, 42 U.S.C. § 1395ii. Under section 405(h), "No action against the United States, the Commissioner of Social Security [Secretary of Health and Human Services], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." Instead, judicial review is only available after the administrative procedures are exhausted and under the administrative standard of review provided by 42 U.S.C. § 405(g).

The United States Supreme Court made this jurisdictional limit clear in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 120 S.Ct. 1084 (1999). That case involved an association of about 200 Medicare-participating nursing homes that needed a determination that various Medicare regulations violated federal statutes and the UNITED

STATES CONSTITUTION so that they could engage in advance planning. In dismissing the claims for lack of jurisdiction, the Court held that the plaintiff had to use the particular review channel that the Medicare statutes create. *Id.*, 529 U.S. at 6. This is because Congress has made a legislative judgment that the complex interrelated regulations that make up the Medicare program should be applied, interpreted, or revised by the agency with specialized knowledge in the first instance, even if this causes individual, delay-related hardship for claimants. *Id.*, 529 U.S. at 13.

The Court, reexamining its earlier cases, rejected all distinctions among types of claims, stating that they all have been relegated to the administrative procedure. *Id.*, 529 U.S. at 13-14. The Court also rejected any distinction between claims of Medicare patients and claims of Medicare providers. *Id.*, 529 U.S. at 18. Neither is there a distinction between disputes that involve only a particular claimant versus a more general dispute affecting the agency's regulatory authority over multiple patients or providers. *Id.*, 529 U.S. at 18-19.

The jurisdictional analysis instead involves the following issues:

- Do the Social Security statutes provide both the standing and the substantive basis for the presentation of the claims?
- Would dismissal of the claim be equivalent to the total preclusion of judicial review?

There is no question that the Social Security statutes provide standing[1] and the

[1] Defendants have challenged the Plaintiff's standing. For purposes of argument, however, if standing exists, it exists under the Social Security statutes.

substantive basis for the Plaintiff's claims. With respect to the eventual availability of judicial review, the Court was clear that the judicial review made applicable by 42 U.S.C. § 405(g) is sufficient after administrative remedies have been exhausted. *Illinois Council*, 529 U.S. at 20-21.

> [I]t is the "action" arising under the Medicare Act that must be channeled through the agency. After the action has been so channeled, the court will consider the contention [that is not suited to administrative review] when it later reviews the action. And a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide, including, where necessary, the authority to develop an evidentiary record.
>
> Proceeding through the agency in this way provides the agency the opportunity to reconsider its policies, interpretations, and regulations in light of those challenges.

Illinois Council, 529 U.S. at 23-24 (citations omitted). Thus, this question is only a matter of whether there is no access to any applicable administrative review procedure or whether a hardship caused by the administrative procedure is so extreme as to turn what is a channeling requirement into "complete" preclusion of judicial review. *Id.*, 529 U.S. at 22-23.

Plaintiff is a Texas for-profit member-owned independent pharmacy cooperative operating in seven states, including Texas. D.E. 1. It is made up of over 500 independent pharmacies who participate as Medicare providers under the Part D prescription drug benefit. Plaintiff complains that it is not accorded administrative review, and thus access to judicial review through 42 U.S.C. § 405(g), because: (1) as an association, the regulations do not recognize it as a potential claimant; and (2) its claims go to the overall

structure of benefit regulations rather than a simple coverage determination.

The Supreme Court, in *Illinois Council*, gave little attention to the "association" complaint of the nursing home association. Noting that the association's standing is based only on the specific injury allegedly suffered by each association member, the Court held that the member's administrative procedure rights adequately protected their individual claims. 529 U.S. at 24. A more thorough review of the issue was required in United States Court of Appeals cases that have since followed, such as: *American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.C. Cir. 2002); *American Chiropractic Association, Inc. v. Leavitt*, 431 F.3d 812 (D.C. Cir. 2005) and *National Athletic Trainers' Ass'n, Inc. v. U.S. Department of Health and Human Services*, 455 F.3d 500 (5th Cir. 2006).

The court in *American Lithotripsy* evaluated the plaintiff's ability to challenge the regulatory interpretation of the Stark Law[2] to preclude reimbursements for physician referrals to their own lithotripsy centers, where kidney stones would be treated and broken down, to be eliminated from the patient's body without necessity of surgery. The court found that the society members did not have standing to challenge the regulations in an administrative proceeding because they were not "providers" under the Medicare statute. *American Lithotripsy, supra* at 30. Because of the economics peculiar to lithotripsy procedures and their more profitable surgical alternatives, the court found that hospitals that had lithotripsy centers "under arrangement" did not have financial

[2] The Stark Law had been passed to curb the overutilization of medical services by physicians who referred patients to facilities in which they had a financial interest for purposes of their own financial gain rather than for proper treatment of the patient's actual needs. *Colorado Heart, infra* at 32.

incentives to contest the new regulation as proxies for the society members.

The evidence that was presented to the court showed that, if the doctors who owned the lithotripsy centers referred patients in violation of the regulations in order to test them, they risked statutory penalties of up to $15,000 per bill, disgorgement of payments received from hospitals, criminal penalties, and exclusion from participation in any federal health care program. *American Lithotripsy*, *supra* at 29-30. The defendants did not dispute this evidence. *Id*. The court then held that the prospect of such financial ruin and major penalties made administrative procedures, for all practical purposes, unavailable, including the judicial review that would follow. *Id*. Thus, the court found that it had jurisdiction despite the exhaustion rule.

In *American Chiropractic*, an association of chiropractors sought a determination that the Secretary of Health and Human Services misinterpreted the Medicare Act in approving certain spinal manipulations by medical doctors and osteopaths. Like *American Lithotripsy*, the jurisdictional dispute centered on whether the association could get its claims heard administratively. *American Chiropractic*, *supra* at 816-17. The association's first issue was that the regulations were being interpreted to require medical doctors or osteopaths to make a referral of a spinal manipulation to a chiropractor before the procedure would be covered and reimbursed. The court held that the chiropractors could induce patients to get their spinal manipulations without the required referral. Upon Medicare's denial of the claim, the chiropractors could take an assignment of the claim from the patient and file an administrative coverage dispute under 42 U.S.C. §

1395w-22(g)(5), aggregating claims if necessary to satisfy the jurisdictional amount requirement.

The D.C. Circuit admitted that the second claim was "more difficult." *American Chiropractic, supra* at 817. That claim asserted that medical doctors and osteopaths should not be permitted to perform the spinal manipulations at all. While a somewhat convoluted set-up, the Secretary of Health and Human Services argued that chiropractors could test this issue. They could provide spinal manipulations to patients who were enrolled in HMO plans that required the use of medical doctors or osteopaths (and did not allow coverage for chiropractors to perform the service). The Medicare Act permitted such a distinction among spinal manipulation providers, but only twenty-two percent of HMO plans had this requirement.

The D.C. Circuit accepted this roundabout path for setting up a coverage dispute that could be channeled to the agency under administrative procedures. The *Illinois Council* requirement of access to post-administrative judicial review of were met. Administrative review was available to the chiropractors, who could take an assignment of the HMO patient's claim for reimbursement. *American Chiropractic, supra* at 817-18. It did not matter that such HMO plans were clearly a small portion of the number of available plans.

In *NATA*, the association (NATA), sought to enjoin enforcement of a Medicare regulation interpreting the Stark Law, which would eliminate reimbursements for athletic trainers who provided occupational or physical therapy incident to a physician's service. Because the athletic trainers worked "incident to" the physician's services, the parties

agreed that the NATA members could not obtain administrative review—they were neither patient beneficiaries nor providers under the Medicare reimbursement structure and would not be in a position to take an assignment of a claim. *NATA, supra* at 504.

So the question for the Fifth Circuit's adjudication was whether it was sufficient under the constraints of *Illinois Council* that NATA's claims could be brought by a third party. *Id*. In particular, a physician could have an athletic trainer perform physical therapy and then the physician could submit a reimbursement claim, knowing that it would be denied. The physician would then have the right of administrative review.

The Fifth Circuit rejected NATA's concern that this scheme placed physicians at risk of civil or criminal penalties for making false claims for reimbursement (as was demonstrated in *American Lithotripsy*). After all, the physicians knew that the athletic trainer's services were not reimbursable. The Court was satisfied, however, that all factual matters could be truthfully set forth in the claim and a special code could be appended to the claim, signaling to the agency that the claim was being made to test the rules. In other words, the agency provided advice for submitting such a test claim and if the claim was submitted in reliance on that advice, a finding of knowing false or fraudulent claims activity was not likely. *NATA, supra* at 507. So the conclusion was that it was possible that the complaint could be tested by a third party—the physician who employed the athletic trainer.

The only other issue that NATA raised was that it made no difference if another party ***could*** bring the claim; the administrative review would only be triggered if that party ***would*** bring the claim. In other words, did physicians have an incentive to bring

such a claim for the benefit of the athletic trainers? The Fifth Circuit held that the fact that the use of athletic trainers reduced the physician's costs was sufficient incentive for them to manufacture the necessary scenario to trigger and prosecute a claim through the administrative process. Furthermore, "a sufficient period of time has not elapsed for us to infer from the lack of a challenge that there will be no challenge." *Id*. at 507. Thus NATA's claims were dismissed for lack of jurisdiction.

More recently, two federal district courts have faced this jurisdictional issue: *Colorado Heart Institute, LLC v. Johnson*, 609 F. Supp. 2d 30 (D.D.C. 2009) and *Physician Hospitals of America v. Sebelius*, 770 F. Supp. 2d 828 (E.D. Tex. 2011). While both addressed the regulatory interpretation of the Stark Law, the jurisdictional decisions were not the same.

In *Colorado Heart*, physicians complained of an interpretation of the Stark Law that would prohibit them from referring their patients to their own physician-owned treatment centers. This case specifically involved the utilization of physician-owned cardiac catheterization laboratories (cath labs). Like the decision in *NATA*, the *Colorado Heart* opinion holds that the cath labs operate at a lower cost than the hospitals would otherwise pay. So the hospitals could file an administrative claim to raise the Stark Law issue and, if required for the analysis,[3] would have a proper incentive to do so. *Colorado Heart, supra* at 37. Thus the court did not have jurisdiction.

[3] The D.C. District Court questioned whether the incentive portion of the Fifth Circuit's analysis applied in the D.C. Circuit, but held that, if it did, the requirement was satisfied.

Physician Hospitals also challenged the regulatory interpretation of the Stark Law that prohibited Medicare reimbursements for self-referrals. *Physician Hospitals, supra* at 829. The case offered a twist, however. The Plaintiffs complained that the exhaustion of administrative remedies posed a "hardship" because they had already invested considerable time and money in a planned expansion of facilities and, they alleged, the Stark Law interpretation was unconstitutionally restricting continuation of the expansion plans. *Id*. at 829.

First, the District Court for the Eastern District of Texas noted that the exhaustion rule is "virtually absolute and applies regardless of the basis of the challenge" and is not excused "even if the Secretary has no authority to grant the requested relief." *Id*. at 830. The court then went on to equate the hardship complaint with the *Illinois Council* "complete denial of judicial review" exception to the exhaustion requirement. The court observed that, if the plaintiff made an administrative complaint and lost on the merits, it would have not only gambled the resources spent in continuing expansion plans during the review process, but like the plaintiff in *American Lithotripsy*, would "forfeit its ability to bill Medicare for any future self-referrals." *Id*. at 831. It considered this a "death penalty sanction" suffered in order to use administrative channels. *Id*. at 832. The motion to dismiss for lack of jurisdiction was denied.

IV. Application of Principles to This Case

Plaintiff claims that it falls within the Illinois Council exception to the exhaustion rule because it is "undisputed" that neither Plaintiff nor its independent pharmacy members could bring a complaint through administrative channels because such a right is

reserved exclusively to the part D eligible individual (the patient). D.E. 27, p. 18 (citing 42 C.F.R. § 423.566(b); 42 C.F.R. § 423.2008(a)). Plaintiff goes on to argue that a hypothetical enrollee in a preferred pharmacy plan could not act as its proxy (by triggering a claim by filling a prescription at an independent pharmacy) because the claim is not a simple matter of a "coverage determination" but implicates an entire regulatory benefit design, which is a "grievance," and is not assignable. Plaintiff further argues that such a patient would not be able to meet the minimum financial amount in controversy and would have no incentive to pursue the matter.

A. Plaintiff's Right to Invoke Administrative Procedures Individually or By Proxy

Plaintiff contends that the administrative procedures for challenging regulations under the Medicare Act that have been available in other cases are not available here because of the provisions peculiar to Medicare Part D. In particular, Plaintiff asserts that disputes regarding co-pays and coinsurance would be treated as grievances related to the "benefit design" of the plan rather than as "coverage decisions." Only coverage decisions, the argument continues, trigger the administrative review that must be exhausted under *Illinois Council*. Plaintiff cites examples in which challenges to a matter deemed a "benefit design" is to be treated as a grievance, which does not trigger the administrative review process.

Defendants respond with reference to 42 C.F.R. § 423.566, which clearly states that a dispute over the amount of cost sharing for a drug under Medicare Part D is a "coverage determination" that can be appealed administratively. 42 C.F.R. §

423.566(b)(5). Ultimately, judicial review is available for coverage determinations, pursuant to 42 U.S.C. §§ 1395w-104(g) and 1395w-22(g)(5). While it may be possible to say that the examples cited by Plaintiff indicate some ambiguity based upon the reasoning behind the dispute, the plain language of the regulation indicates that Plaintiff's claims would be included as a "coverage determination." Moreover, Defendants have offered the interpretation of Anthony Culotta, Director of the Medicare Enrollment and Appeals Group at the Centers for Medicare and Medicaid Services, stating that the Plaintiff's challenge would be treated as a coverage determination subject to administrative review. D.E. 19-1.

Considering the plain language of the regulation, the assurances of the Medicare official, and the Fifth Circuit's demonstrated deference to agency representations regarding the manner in which the program will be executed, the Court is of the opinion that the administrative process is available to make a determination on the issues in this case in the first instance. *See generally, NATA, supra* at 506 (absent evidence of a reason to doubt agency interpretation, such interpretation can be credited). If, for any reason, the agency refuses to process the claim as a coverage determination, then Plaintiff retains the ability to reassert its right to judicial review by re-filing this claim with that new evidence.

That same section, 423.566, specifies that such an appeal may be brought by the plan enrollee or his or her appointed representative. 42 C.F.R. § 423.566(c). Specifically, the Medicare Part D Manual, § 10.4.1, which is available to the public at http://www.cms.gov/MedPrescriptDrugApplGriev/10_FederalCourtReview.asp#TopOfPage and

which is entitled, "Representative Filing on Behalf of the Enrollee," allows an enrollee to appoint a representative to act on his behalf and notes that an employee of a pharmacy can act as such representative.

Granted: the appointment of a representative is not the same as the assignment of the claim; with "assignments" being used in some of the case law discussed above to give those plaintiffs administrative review rights. But for purposes of exhausting administrative remedies, that is a distinction without a difference.

While assignment of the enrollee's claim was considered the vehicle for administrative review in the *American Chiropractic* case, nothing about that decision indicates that assignment was the *sine qua non* of the exhaustion rule's application. In *NATA*, the regulatory challenge could be made by the physicians who employed the athletic trainer. No assignment of the claim was considered necessary because the question posed by *Illinois Council* was whether the claim could be channeled through the administrative review process and ultimately lead to judicial review—without regard to who might shepherd that claim through the process. *NATA*, *supra* at 404-05.

This issue was considered head-on in *Colorado Heart*, where the physicians sought to challenge the prohibition against referring patients to their own cath labs but, as agreed by the parties, had no right to do so through the administrative process. Comparing *American Chiropractic* to *NATA*, the court held, "Plaintiffs' lack of a direct avenue to administrative review through an assignment does not mean that they could not get their claim heard." *Colorado Heart*, *supra* at 37. Finding that the hospitals had

sufficient incentive to bring the claims, the hospitals were adequate proxies without necessity of assignment.

Here, the independent pharmacies would have to demonstrate, consistent with their burden of proof, that patients enrolled in preferred pharmacy plans could not or would not bring the instant claims. Because the Defendants have shown that patients could bring the claims and could even appoint pharmacy employees as their representatives, Plaintiff has not met its burden to show that its claims cannot be prosecuted.

B. No Claim Would Satisfy the Minimum Requirements for Amount in Controversy

It is undisputed that, in order to be entitled to judicial review at the end of the administrative process, the Plaintiff's (or Plaintiff's proxies') claim (or aggregate of claims) must involve an amount in controversy of $1,300 or more. 42 C.F.R. §§ 423.1976(a),(b), 423.2136(a); 75 Fed. Reg. 58407 (threshold of $1,300 for 2011). Certain claims and appeals may be aggregated in order to meet the minimum amount in controversy, although there are very specific limits with respect to which matters may be combined: appeals involving the same drug, with administrative appeals filed within 60 days of the coverage determination. 42 C.F.R. § 423.1970(c)(1). Defendants do not dispute these limitations on aggregation of appeals. D.E. 28, p. 11.

Using the Humana Walmart preferred pharmacy program as an example, Plaintiff argues that it would take 50 prescription disputes or total prescription claims of at least $7,647.66 to generate the $1,300 minimum amount in controversy. Plaintiff argues that

the task of orchestrating a concert of action to meet this threshold for judicial review is impossible or nearly impossible.

Defendant responds that patients enrolling in Medicare Part D tend to be elderly or disabled and thus take a large number of prescriptions or have high drug costs. Most compelling is Defendant's argument that some prescription drugs are so costly that meeting the threshold amount in controversy is not nearly as difficult as Plaintiff makes it out to be. In particular, Defendant attaches a Minute Order in *Back v. Sebelius*, No. EDCV 09-01706 in the United States District Court for the Central District of California dated January 4, 2011. D.E. 28-1. That Order discusses a single medication for a hospice patient that, in a single month, cost almost $6,000. That is not to say that, if covered, the co-pay or coinsurance for that prescription would be more than $1,300 or that the difference between having the prescription filled in a preferred pharmacy versus an out-of-network pharmacy would be $1,300. But it does raise a significant, unanswered question that, on this record, requires the Court to give the benefit of a doubt to the Defendants, based upon the Plaintiff's burden of proof to establish jurisdiction.

C. No Proxy Would Have Incentive to Prosecute the Claim

Last, Plaintiff argues that, even if its rights are dependent upon another party acting as proxy and even if that proxy could establish the amount in controversy, the proxy does not have sufficient incentive to prosecute the claim. The Fifth Circuit, for instance, made this an issue in *NATA*, when it held that the physician-proxies would have an incentive to prosecute the athletic trainers' claims because they employed the athletic

trainers at a lower cost such that it was in their own financial interests to be able to continue using athletic trainers.

Plaintiff argues that (1) the patients have made a choice to enroll in a program that provides for a preferred pharmacy co-pay or coinsurance structure, which indicates some complacency with the pharmacy distinction issue; (2) the amounts at issue are too small to motivate individual patients; and (3) they would not want to have to deal with the hassle of prosecuting the claims. The first issue is not credible, given that it argues against the Plaintiff's members' own business model and contradicts the Plaintiff's pleading regarding the benefits lost to patients by having to use "preferred" pharmacies rather than their own independent neighborhood pharmacies. The second issue, as discussed above, is questionable. The third issue is controverted by the fact that the patient can appoint a representative, such as a pharmacy employee, to prosecute the claim for him or her. Once again, based upon the burden of proof being on the Plaintiff, the Court is not convinced that there are insufficient incentives for proxies to assist in getting the Plaintiff's claims heard.

For these reasons, the Defendant's Motion to Dismiss (D.E. 19) is GRANTED and the Plaintiff's claims are DISMISSED for lack of jurisdiction.

ORDERED this 5th day of December, 2011.

Nelva Gonzales Ramos

NELVA GONZALES RAMOS
UNITED STATES DISTRICT JUDGE